510(k) SUMMARY

JUL 15 2003

DENTSPLY

NAME & ADDRESS:

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K031145

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: April 9, 2003

TRADE OR PROPRIETARY NAME: eSTYLUS™ ELECTRIC MOTOR SYSTEM

CLASSIFICATION NAME: Dental handpieces and accessories (872.4200)

PREDICATE DEVICES:

Bien-Air's Dental Handpieces	K983183
TCM Endo III Dental Handpiece	K013185

DEVICE DESCRIPTION: The eSTYLUS™ ELECTRIC MOTOR SYSTEM is an electric motor driven dental handpiece system with various attachments, intended for use in general and endodontic dentistry. The System includes the electric motor, control unit, AC power supply, connector hose, and contra-angle and straight attachments.

INTENDED USE: The eSTYLUS™ ELECTRIC MOTOR SYSTEM is designed for use in general dentistry and endodontic dentistry for cutting, shaping, filing, drilling, cleaning and polishing procedures.

TECHNOLOGICAL CHARACTERISTICS: The eSTYLUS™ ELECTRIC MOTOR SYSTEM is substantially equivalent to Bien Air's dental handpieces and Nouvag's TCM Endo III dental handpiece. They have the same intended uses, basic technology, primary energy source, and materials. Similar materials, features,

We believe that the similarities to legally marketed predicate devices, the comparison and performance data provided, and the testing conducted support the safety and effectiveness of the eSTYLUS™ ELECTRIC MOTOR SYSTEM for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2003

Mr. P. Jeffery Lehn
Director of Compliance & Regulatory Affairs
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K031145
Trade/Device Name: eSTLUS™ ELECTRIC MOTOR SYSTEM
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: April 9, 2003
Received: April 16, 2003

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K031145

Device Name: eSTYLUS™ ELECTRIC MOTOR SYSTEM

Indications for Use:

Used in general dentistry and endodontic dentistry for cutting, shaping, filing, drilling, cleaning and polishing procedures

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K031145